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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,924	11/21/2003	John P. Donoghue	8790.0011-00	7558

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EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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07/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/717,924

Applicant(s)

DONOGHUE ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-149 is/are pending in the application.
- 4a) Of the above claim(s) 1-49 and 109-141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-60, 62-108 and 142-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 5/07/2007 in which claims 142 and 147 were amended and claim 61 was cancelled. Currently claims 1-60 and 62-149 are pending for examination in this application with claims 1-49 and 109-141 are withdrawn from a previous election restriction.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-60, 62-107 and 142-149 are rejected under 35 U.S.C. 102(b) as being anticipated by Elsberry et al. (6,094,598). Elsberry et al. discloses a method of treating movement disorders via brain stimulation.

Regarding claims 50-60, 62-107 and 142-149, Elsberry et al. discloses a sensor (130, 38, 40) configured to be proximate to a first part of the body generating electric signals and to detect the electric signals, a first processor (100) connected to the sensor for processing detected electrical signals, a device (10) configured to receive the first control signal and be controlled by it, and a second (140) processor configured to generate a second signal based on a monitored parameter of the sensor to a first (10) and second device (16) with processor (200) to provide information relating to delivery of an agent, wherein the sensor is capable of detecting brain neural signals, voluntary

control signals, nerve signals, tumor signals, EEG signals, neuron spikes and local field potentials (col 4, ln 28-70, col 5, ln 1-35) (see figures 1-2). The computer system is capable of using the control signal information to store data relating to agent delivery and control delivery based information for controlling in response to a sensed condition (col 5, ln 35-70) with a drug (see tables 1-3) being dispensed from a selection of agents and dosages (col 5, ln 45-70) via a agent delivery unit (10, col 6, ln 1-10). Additionally, Elsberry et al. uses a digital-analog converter to convert the signals from sensed signals to control values for the agent delivery system (col 5, ln 35-50).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 60 is rejected under 35 U.S.C 103(a) as being unpatentable over Elsberry et al. in view of Shenoy et al. (6,731,964). Elsberry et al. meets the claim limitations as described above except for control over a prosthetic limb.

However, Shenoy et al. teaches methods of using processed neural signals.

Regarding claim 60, Shenoy et al. teaches the use of sensed neural signals to control a prosthetic arm (Figure 1).

At the time of the invention, it would have been obvious to add the functional limb control of Shenoy et al. to the system of Elsberry et al. in order to aid in movement control of patient who may be suffering from a muscular control disease. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Shenoy et al.

***Claim Rejections - 35 USC § 103***

Claims 86, 88 and 108 are rejected under 35 U.S.C 103(a) as being unpatentable over Elsberry et al. in view of Fischell et al. (2003/0139778). Elsberry et al. meets the claim limitations as described above except for wireless communication controller with a display.

However, Fischell et al. teaches a response system for detection and treatment.

Regarding claims 86, 88 and 108, Fischell et al. teaches a wireless control system (53,54) that uses a display system for external patient control over an implanted system (Figure 1).

At the time of the invention, it would have been obvious to add the wireless controller of Fischell et al. to the system of Elsberry et al., because the wireless controller would allow for physician intervention without invasive surgery. The references are analogous in the art and with the instant invention; therefore, a

combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Fischell et al.

***Response to Arguments***

Applicant's arguments, see remarks, filed 5/07/2007, with respect to claims 98-102 have been fully considered and are persuasive. The objection of these claims has been withdrawn.

Applicant's arguments filed 5/07/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that Elsberry et al. (6,094,598) fails to disclose at least a second processor configured to generate a second control signal based on a monitored parameter of a device and the processor configured to provide information relating the delivery of an agent to the body to second device based on the second control signal.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that Elsberry et al. (6,094,598) discloses the subject matter as claimed, regarding the second processor and device Examiner asserts that "...at least a second processor (140) configured to generate a second control signal based on a monitored parameter of a device (sensor 130) and the processor configured to provide information relating the delivery of an agent to the body to second device (16) based on the second control signal..." Regarding claim 50, the second processor (140) a A-D converter receives a control signal (sensor output) from the sensor (130) and converts it

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to another control signal (modified sensor output) to which first processor (100) creates and output control signal which used to run the drug pump in closed loop drug delivery (col 8, ln 10-20) (Figure 2). Examiner considers the electrical energy and input/output from each processor as a control signal for control over the pump assembly and electrical assembly. Regarding claim 142, Elsberry et al. discloses a second device (16) which is coupled the sensor (130) for additional treatment in conjunction with the first device (10) in which the processors (100, 140, 200) are interconnected to each through the sensor and different control signals sent to the devices (10,16) and therefore are interrelated to each other (cols 8-10) during treatment by either pre-programmed protocols or clinician access (Figure 2).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/23/07

  
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